

# Mona Lisa N.V.

Kapelstraat 1, 3540 Herk-de-Stad, Belgium

Device Identification:

Sterile Mona Lisa® CuT 380A, T-Safe® CU 380A, T-Protect® CU 380A,  
Mona Lisa® CuT 380A QL, T-Safe® CU 380A QL, and MI-MONA®-T 380

Intrauterine devices.

All the above IUD's are supplied with or without Hysterometer size 12  
in a separate sterile pouch.

Intended Purpose of Device:

Copper-containing intrauterine devices intended for long-lasting  
reversible female contraception

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on Medical Devices, Annex II, Section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the  
above device has been examined and, based on the evidence submitted, it is considered that the  
device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance  
system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 09 December 2020 until 20 April 2023

Issue 3. Certified since 20 April 1998

and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered BE/AND 202064 dated 06 April 2018

Authorised by

### SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4, EN rev. 02

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## Directive 93/42/EEC on Medical Devices, Annex II, Section 4

### Issue 3

Addenda to that report have been issued on the following dates:

<u>Addendum Date</u>	<u>Reason for Addendum</u>
13 November 2018	The use of DuPont Tyvek® (MPTP) transition material
12 August 2019	Change of the address
20 November 2019	Addition of the new brand name
08 January 2020	Change to labelling to included specific reference to the product including a Size 12 Hysterometer
06 May 2020	Change of supplier for the polyamide (Nylon) withdrawal thread
	Validation of a dedicated load ethylene oxide sterilization cycle at Sterigenics (Petit Rechain)
03 November 2020	Change of brand names

